

REMARKS

Claims 1-29 are pending in the instant application. Claims 1-29 stand rejected under 35 U.S.C. §112, second paragraph. Claims 1-7, 9, 12, 16-18, 21, 23, 27, and 28 stand rejected under 35 U.S.C. §102(e) as being anticipated by United States Patent No. 6,426,058 to Pines et al. Claims 1-7, 9, 12, 16-18, 21-23, 27, and 28 stand rejected under 35 U.S.C. §102(e) as being anticipated by United States Patent No. 6,278,893 to Ardenkjaer-Larson et al. Claims 1-29 stand rejected under 35 U.S.C. §102(e) as being anticipated by United States Patent No. 6,574,496 to Golman et al. Claims 8, 14, 15, 19, 20, 24-26, and 29 stand rejected under 35 U.S.C. §103(a) as being unpatentable over United States Patent No. 6,426,058 to Pines et al. Claims 10, 11, and 13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pines in view of United States Patent No. 6,103,492 to Yu. Claim 1 has been amended. None of the amendments constitute new matter in contravention of 35 U.S.C. §132. Reconsideration is respectfully requested.

Claims 1-29 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention. This rejection is respectfully traversed.

The examiner has maintained the clarity objection in relation to the term “assay” in claim 1, stating that an assay must include some steps. Applicants respectfully submit that the amendments to Step (a) of Claim 1 overcome this rejection. Reconsideration and withdrawal of the rejection are respectfully requested.

The examiner also objects to step (d) of claim 1 for not stating what steps are required to generate further assay results. Applicants respectfully submit that such is not necessary and to the point of the claim element. The step of step (d) is ‘utilizing’ the NMR data obtained in step (c) for further assay results. As such, the claim properly states the present invention. Reconsideration and withdrawal of the rejection are respectfully requested.

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The examiner has maintained the clarity objection to the term “known assay techniques without hyperpolarisation” in claim 15. Claim 15 has been amended so as to compare the improved signal-to-noise ratio to that of the present claim without the use of hyperpolarization. Reconsideration and withdrawal of the rejection are respectfully requested.

The examiner has maintained the clarity objection to the term “other suitable container” in claim 28, stating specifically that the claims do not recite what the containers are suitable for. Claim 28 has been amended to recite a ‘container suitable for carrying out the hyperpolarization of step (b). Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1-7, 9, 12, 16-18, 21, 23, 27, and 28 stand rejected under 35 U.S.C. §102(e) as being anticipated by United States Patent No. 6,426,058 to Pines et al. Claims 1-7, 9, 12, 16-18, 21-23, 27, and 28 stand rejected under 35 U.S.C. §102(e) as being anticipated by United States Patent No. 6,278,893 to Ardenkjaer-Larson et al. These rejections are respectfully traversed.

Pines discloses performing an assay using an assay reagent containing at least one NMR active nucleus which is hyperpolarized and then analyzing the assay reagent and/or the assay by NMR .

Ardenkjaer-Larson discloses performing an assay using an assay reagent containing an NMR active nucleus, hyperpolarizing the nucleus, and analyzing the assay by NMR.

The present invention, conversely, claims an in-vitro assay method which includes the steps of performing an assay on a biological species using an assay reagent containing at least one NMR active nucleus which is hyperpolarized and analysing the assay reagent and/or the assay by NMR for a physical or chemical change in said biological species that is independent of the interaction of the biological species with the NMR active nucleus.

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In rejecting the present invention, the examiner states that the prior art discloses a test in which a physical or chemical change in a biological species is involved upon introduction of an NMR active nucleus to a biological species. Claim 1 has been amended to recite that the present invention is evaluating a physical or chemical change in a biological species that is independent of the interaction of the biological species with the NMR active nucleus. The Examiner is respectfully referred to page 7, lines 13-28 of the instant application for details of exemplary assays of the present invention each of which provides evaluation of a physical or chemical change in a biological species that is independent of the interaction of the biological species with the NMR active nucleus. Furthermore, in each case some form of deliberate intervention is involved over and above the interaction of the biological species with the NMR active nucleus and the magnetic resonance evaluation. The prior art methods evaluate the inherent properties of a biological species as opposed to any physical or chemical changes taking place therein and no additional intervention is involved other than the interaction of the biological species with the NMR active nucleus and the magnetic resonance evaluation.

Therefore, as both Pines and Ardenkjaer-Larson both fail to disclose an analysis of a physical or chemical change in a biological species that is independent of the interaction of the biological species with the NMR active nucleus, both references fail to disclose each and every element of the independent claim. Moreover, neither Pines nor Ardenkjaer-Larson disclose, teach, or suggest such analysis. As a result, Applicants respectfully submit that the present invention is patentably distinct over both Pines and Ardenkjaer-Larson.

Reconsideration and withdrawal of the rejections are respectfully requested.

Claims 1-29 stand rejected under 35 U.S.C. §102(e) as being anticipated by Golman *et al* (US 6574496). This rejection is respectfully traversed.

First, Applicants note that the Examiner has provided no basis for this rejection. All that is provided is a conclusory statement that does not address the elements of the present invention. "It is incumbent upon the Patent Office in the first instance to set forth clearly

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why it regards a claim to be anticipated, obvious, or otherwise defective. The pertinence of each reference, if not apparent, must be clearly explained.” *In re Mullin, Wetherby, and Chavalier*, 179 USPQ 97, 100 (CCPA 1973). That said, the method of Golman involves the administration of a magnetic resonance imaging agent to a sample and subsequently detecting signals from the imaging agent. As discussed for Pines and Ardenkjaer-Larsen above, Golman fails to disclose a method of magnetic resonance investigation involving an assay, as defined in the present invention, which results in a physical or chemical change involving a biological species independent of the interaction of the biological species with the NMR active nucleus. Moreover, Golman fails to disclose, teach, or suggest such an analysis. As a result, Applicants respectfully submit that the present invention is patentably distinct over Golman. Reconsideration and withdrawal of the rejection are respectfully requested..

Applicants again submit, as Golman fails to disclose each and every element of the claimed invention, the present invention is novel thereover. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 8, 14, 15, 19, 20, 24-26, and 29 stand rejected under 35 U.S.C. §103(a) as being unpatentable over United States Patent No. 6,426,058 to Pines et al. Claims 10, 11, and 13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pines in view of United States Patent No. 6,103,492 to Yu. These rejections are respectfully traversed.

Each of the rejections under 35 U.S.C. §103 cover dependent claims. “A dependent claim should be considered allowable when its parent claim is allowed.” *In re McCarn*, 101 USPQ 411, 413 (CCPA 1954). Applicants respectfully submit that as the patentability of the underlying independent claim 1 has been demonstrated above, that the dependent claims must therefore be patentable as well. Reconsideration and withdrawal of the obviousness rejections over Pines and Pines in view of Yu are respectfully requested.

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In view of the above amendments and remarks, Applicants respectfully submit that the instant application, including claims 1-29, is in condition for allowance. Favorable action thereon is respectfully requested.

Any questions with respect to the foregoing may be directed to Applicants' undersigned counsel at the telephone number below.

Respectfully submitted,



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